

REMARKS

Status of the Claims

Claims 1-6, 9-13, 20 and 23-27 are pending in the present application, with claims 1 and 20 being independent claims. Claims 1 and 20 are amended. New claim 28 is presented. Reconsideration of claims 1-6, 9-13, 20 and 23-27, and examination of claim 28, is respectfully requested.

Summary of Examiner Interview

On August 8, 2006, Applicant's representative, Charlton Shen, conducted a telephone interview with Primary Examiner Alvin J. Stewart to discuss the prosecution of the present application. The Applicant's representative summarized Claim 1 and distinguished it from the teachings of U.S. Patent No. 6,110,212 to Gregory. Examiner Stewart suggested some potential amendments, which would clarify the distinction between the pending claims and Gregory. These amendments are entered and discussed herein.

Amendments to the Claims

To expedite prosecution of this application, Applicants present the following amendments without prejudice. Such amendments, however, provide no evidence regarding the propriety of any rejections regarding the present claims in light of the cited art. Applicants maintain the right to pursue any of the present claims in one or more continuing applications.

Claim 1 is amended to recite a biocompatible tissue implant comprising "a *naturally occurring* biological tissue slice." Support for the amendment can be found throughout the present application, though Applicants specifically point to Examples 1, 2, and 3 that describe the use of naturally occurring bovine tissue slices (e.g., anterior cruciate ligament, meniscus, and cartilage) and paragraph [0056]. The tissue slice also includes "an effective amount of viable cells *that naturally occur within the tissue slice*." Support for the amendment can be found throughout the present application, though Applicants specifically point to paragraph [0012], which discusses that tissue slices harvested from viable, healthy tissue can act as a cell source

without the cost of cell isolation and amplification (i.e., the cells in the tissue slice are naturally occurring).

Claims 20 is similarly amended to include the recitations discussed for claim 1.

As such, the claim amendments do not add new matter.

Nonobviousness

Claims 1-6, 9, 10, 20 and 23-25

Claims 1-6, 9, 10, 20 and 23-25 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,110,212 to Gregory (herein “Gregory”) in view of U.S. Patent 5,735,903 to Li et al. (herein “Li”). The claims, however, are all patentable because neither Gregory nor Li teach a tissue implant comprising a naturally occurring biological tissue slice including viable cells that naturally occur within the tissue slice, as recited in the pending claims.

Applicants maintain that claim 1, in its previous forms, is patentable over the cited art for at least the reasons stated in previously submitted papers. For example, as discussed in Applicants’ paper dated March 20, 2006, a tissue implant comprising “a natural biological tissue slice” is distinct from the teachings of Gregory because the reference only teaches the formation of artificially-formed, three-dimensional stromal cell systems that can in no way be interpreted as natural. Indeed, this distinction has not been contradicted in the pending Office Action. Applicants, however, amend claim 1 consistent with the suggestions of the Examiner during the telephone interview of August 8, 2006, to expedite prosecution of the pending application.

Amended claim 1 is directed toward a biocompatible tissue implant comprising a *naturally occurring* biological tissue slice that includes an effective amount of viable cells *that naturally occur within the tissue slice*. The tissue slice is dimensioned so that the cells can migrate out of the tissue slice to proliferate and integrate with other tissue. The implant also includes a retaining element for securing the tissue slice.

Neither Gregory nor Li teach, suggest, or hint of using a naturally occurring biological tissue slice that includes an effective amount of viable cells that naturally occur within the tissue

slice in a tissue implant. As discussed in Applicants' previous responses, Gregory is directed the use of an elastin or elastin-based biomaterial, which is not a naturally occurring tissue. Gregory suggests that elastin or elastin-based biomaterials can be formed into a three dimensional structure that may be populated with stromal cells, growth factors, and regulatory factors (see Gregory, column 3, lines 22-29). As discussed in Gregory and the associated U.S. patents cited therein (see *id.*, column 3, lines 29-35), these are stromal cell systems that are man-made, artificial constructs – not naturally occurring biological tissue. This is in complete contradistinction with a “naturally occurring biological tissue slice” that includes an effective amount of viable cells that naturally occur within the tissue slice, as recited in amended claim 1.

Li's teachings go no further to disclosing the naturally occurring tissue slice of amended claim 1. Indeed, the Office Action effectively recognizes this by only citing Li to teach securing an implant to a patient's tissue site. Indeed, the implants described by Li are all meniscal augmentation devices that utilize processed natural fibers that in no way can be considered naturally occurring tissue slices with an effective amount of viable cells that naturally occur within the tissue slice.

Accordingly, amended claim 1 is patentable over the combination of Gregory and Li. Since claims 2-5, 9, and 10 all depend from amended claim 1, they are all patentable for at least the same reasons that amended claim 1 is patentable. Claim 2 is also patentable because Gregory and Li do not teach the use of autogeneic tissue, allogeneic tissue, xenogeneic tissue, and combinations thereof. Though Gregory discusses the use of autologously derived *cells for forming* a lining on elastin and elastin-based biomaterial structures; these are not *tissues* as recited by claim 2 (see *id.*, column 3, lines 46-52). Claim 3 is also patentable since Gregory and Li do not reveal the tissue types listed. Claims 4-6 are also patentable since the specific tissue slice dimensions in the claims are not taught by Gregory or Li. Though Gregory discusses the thicknesses of its elastin sheets, such thicknesses are distinguished from the thickness of a naturally occurring tissue slice (see *id.*, column 5, lines 52-62) as recited in the claims.

Amended claim 20 is drawn to a method of repairing a tissue injury or defect that includes providing a biocompatible tissue implant comprising a naturally occurring biological tissue slice having an effective amount of viable cells that naturally occur within the tissue slice. Accordingly, amended claim 20 is patentable over the combination of Gregory and Li for at

least the same reasons that amended claim 1 is patentable. Claims 23-25, depending from claim 20, are also patentable for at least the same reasons.

Claims 11-13, 26, and 27

Claims 11-13 depend from amended independent claim 1, while claims 26 and 27 depend from independent method claim 20. The aforementioned dependent claims stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Gregory, Li, and U.S. Patent No. 6,773,458 to Brauker et al. (herein "Brauker"). Though the Office Action suggests that Brauker teaches the use of minced tissue fragments, the reference does not disclose what Gregory and Li fail to provide in amended claims 1 and 20: a naturally occurring tissue slice. As well, none of Gregory, Li, and Brauker provide any motivation to combine minced tissue fragments with a naturally occurring tissue slice. Clearly, claims 11-13, 26, and 27 are patentable over the combination of Gregory, Li, and Brauker.

New Claim 28


New claim 28, depending from claim 4, recites that the naturally occurring tissue slice is configured as a strip of naturally occurring tissue. Support for the claim can be found throughout the present application, and specifically at paragraph [0033]. The claim is patentable at least for the reasons that claims 1 and 4 are patentable.

CONCLUSION

In view of the remarks above, Applicant submits that claims 1-6, 9-13, 20 and 23-28 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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